

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: ROTAVIRUS VACCINES
ANTITRUST LITIGATION

Civil Action No. 2:18-cv-01734-JCJ

Margiotti & Kroll Pediatrics, P.C.,
on behalf of itself and all other similarly
situated,

Plaintiff,

v.

MERCK SHARP & DOHME CORP.,

Defendant.

Civil Action No.

JURY TRIAL DEMANDED

COMPLAINT – CLASS ACTION

CLASS ACTION COMPLAINT

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1. Margiotti & Kroll Pediatrics, P.C. (“Plaintiff” or “MKPEDS”), individually and on behalf of a class of all others similarly situated, brings this action for treble damages under the antitrust laws of the United States against Merck Sharp & Dohme Corporation (“defendant” or “Merck”). Plaintiff challenges Merck’s anticompetitive scheme to enhance and maintain its monopoly power in the market for rotavirus vaccines sold in the United States (“Rotavirus Vaccine Market”). Plaintiff purchased rotavirus vaccine directly from Merck and brings this action to recover the overcharges that resulted from Merck’s illegal monopolization scheme.

I. INTRODUCTION

2. This action challenges Merck’s anticompetitive vaccine bundling scheme whereby Merck leverages its monopoly power in multiple pediatric vaccine markets to maintain its monopoly power in the Rotavirus Vaccine Market and, consequently, to charge supra competitive prices to purchasers of its rotavirus vaccines.

3. Merck is one of the world’s largest vaccines manufacturers and a leading manufacturer of vaccines in the United States. It is the sole United States manufacturer in the markets for multiple pediatric vaccines, including MMR (measles, mumps, and rubella) and Varicella, holding 100% of United States sales for those vaccines. In addition, Merck dominates United States sales in the market for human papilloma virus (“HPV”) vaccine, with a market share of over 95%. Merck is by far the dominant seller in the Rotavirus Vaccine Market, marketing its vaccine under the trade name RotaTeq; its only competitor in the Rotavirus Vaccine Market is GlaxoSmithKline plc (“GSK”), which markets its rotavirus vaccine under the trade name Rotarix.

4. Indeed, Merck was the only seller of rotavirus vaccine in the United States from 2006 to 2008, which GSK received approval to market Rotarix. Before the threat of competition

from GSK, Merck had contracts that offered “bundled” discounts that would condition prices on loyalty to a bundle of Merck vaccines. In preparation for GSK’s introduction of a competing rotavirus vaccine, Merck added a condition to its contracts that required customers to buy all or nearly all of their pediatric rotavirus vaccines from Merck or face substantial penalties on all other Merck vaccines (the “RotaTeq Bundled Loyalty Condition”). This new bundle (the “Merck Bundle”) meant that any customer who wanted to buy Rotarix from GSK had to be willing to accept substantial penalties on any RotaTeq the customer buys and substantial penalties on all other Merck vaccines (including those for which there is no other supplier). Upon information and belief, the Merck Bundle forecloses competition in greater than 40% of the Rotavirus Vaccine Market.

5. The Merck Bundle substantially foreclosed the Rotavirus Vaccine Market to GSK. For GSK to sell Rotarix to any of Merck’s customers who are subject to the bundled loyalty contracts, GSK would have to cut its prices substantially to *all* its customers, including those customers subject to Merck’s bundled loyalty contracts, those customers subject to GSK’s contracts, and those customers not subject to any vaccine buying contracts. This made it more profitable for GSK to instead adopt a high-price strategy, to maximize revenues in the unforeclosed portion of the market, and not attempt to compete with Merck for sales in the foreclosed portion.

6. The result is that the Merck Bundle substantially forecloses competition by reducing GSK’s incentive to compete based on price, thereby allowing Merck to maintain its monopoly share of the Rotavirus Vaccine Market, and, ultimately, to charge artificially-inflated prices for rotavirus vaccine. Thus, instead of decreasing the price of RotaTeq when GSK entered

the market, as would normally be expected to result from competitive entry into a monopoly market, Merck has maintained and increased the price of RotaTeq.

7. As a result, plaintiff and the proposed class were overcharged having paid artificially inflated prices for rotavirus vaccines.

II. PARTIES

8. Plaintiff is a private pediatric medical practice with seven office locations – in Trevose, Newtown, Warrington, Philadelphia and Horsham, Pennsylvania -- all of which are located in this district. During the class period (defined below), plaintiff purchased RotaTeq directly from Merck and was injured as a result of paying an overcharge due to Merck's anticompetitive conduct.

9. Defendant Merck Sharp & Dohme Corporation, is a company organized under the laws of New Jersey, and headquartered in Whitehouse Station, New Jersey. Defendant Merck sells pediatric vaccines in the United States, including RotaTeq. Merck has facilities in numerous states, including research, development, and manufacturing facilities in this district. In particular, Merck tests and manufactures vaccines at its “West Point” facility in Lansdale, PA, and has a major research facility located in North Wales, Pa.

III. JURISDICTION AND VENUE

10. This allegation alleges violations of sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2, and seeks relief under section 4 of the Clayton Act, 15 U.S.C. § 15(a), to recover treble damages, costs of suit, and reasonable attorneys' fees for the injuries sustained by plaintiff and members of the class. This Court has subject matter jurisdiction over this action pursuant to 15 U.S.C. §§ 4 and 15, and 28 U.S.C. §§ 1331 and 1337.

11. Venue is proper in this district under 15 U.S.C. § 22 and 28 U.S.C. § 1331(b)(1)-(2) because Merck resides in and is an inhabitant of this district or is found or transacts business in this district and because a substantial part of the acts or omissions giving rise to the claims set forth herein occurred in this district.

12. This Court has personal jurisdiction over defendant because during the class period defendant had facilities involved in the research, development, and manufacturing of vaccines in this district; marketed and sold RotaTeq in this district; and has had substantial contacts with this district in furtherance of the anticompetitive activity alleged herein.

IV. INTERSTATE COMMERCE

13. The pharmaceutical products at issue in this case, including RotaTeq, are sold in interstate commerce, and Merck's conduct set forth herein substantially affected interstate commerce throughout the United States and caused antitrust injury throughout the United States.

V. BACKGROUND ON THE MANUFACTURE, REGULATION, AND SALE OF PEDIATRIC VACCINES IN THE UNITED STATES

A. How Vaccines Work

14. Vaccines help a patient develop immunity by, essentially, imitating an infection. A vaccine typically contains an agent that resembles a disease-causing micro-organism, and is often made from a weakened or killed form of the microbe, its toxins, or one of its surface proteins. The agent stimulates the body's immune system to recognize the agent as a threat, and in so doing, causes the body to create antibodies designed to fight the disease-causing organism. Thus, when exposed to a live version of the micro-organism in the future, the vaccinated body's immune system can more easily recognize and destroy these micro-organisms that it later encounters.

15. Because vaccines are meant to stimulate a particular immune response to a particular pathogen, vaccines for one disease (e.g., rotavirus) are not interchangeable with vaccines for another (e.g. polio).

16. Vaccines are manufactured in several different ways. These include live, attenuated vaccines, which contain a version of the living virus that has been weakened so that it does not cause disease, as well as inactivated vaccines, which are made by killing the virus during the process of making the vaccine.

17. For most vaccines – in particular, inactivated vaccines – the first dose does not provide as much immunity as possible. As a result, many vaccines require multiple doses to reach maximum immunity. Booster doses are typically distinct from the initial vaccine given to a patient and can be configured in different ways.

18. Because of the large number of different diseases requiring vaccination, a child often needs multiple vaccines injections during a single visit to the doctor's office. As a result, manufacturers have developed several combination vaccines, which inoculate against multiple diseases with a single dose injection. Combination vaccines are often preferred by parents to stand-alone vaccines because of benefits such as decreased anxiety, perceived reduction in pain for the child, fewer missed opportunities to vaccinate, convenience, and decreased costs as a result of fewer office visits. Benefits to the physicians' office of using combination vaccines include reduced missed opportunities to vaccinate, storage of fewer vials, decreased risk of needle sticks as a result of handling fewer syringes, and potentially improved record keeping and tracking.

B. FDA Approval of Vaccines and CDC Immunization Schedules

19. Vaccines are part of a category of pharmaceutical products known as biologics, or biopharmaceuticals. Biologics are drugs manufactured from biological sources as opposed to drugs that are produced through chemical synthesis. In the United States, both biologics and non-biologic pharmaceuticals are regulated by the Food and Drug Administration (“FDA”). However, biologics and non-biologic pharmaceuticals differ in that biologic products cannot receive FDA approval through the Abbreviated New Drug Application (“ANDA”) process, which allows drugs that are demonstrated to be “bioequivalent” to an approved drug to be marketed as generics. Instead, in 2009, Congress passed the Biologics Price Competition and Innovation Act (“BPCIA”) which provided an abbreviated approval pathway for licensure of biologic products that are “biosimilar” to an approved reference drug. However, even under this abbreviated approval pathway, in order to get FDA approval for a biologic product, a potential biologics manufacturer (“sponsor”) must undertake expensive clinical trials to establish safety, purity, and effectiveness.

20. Vaccine licensure requires clinical trials and extensive lab testing that can take several years for completion. A sponsor who wishes to get approval for a new biologic product must first file an Investigational New Drug (“IND”) application. The IND describes the vaccine, its method of manufacture, and quality control tests for release. After receiving approval for the IND, the sponsor may begin pre-licensure clinical trials in human subjects. There are three phases of clinical trials, each of which expands the number of human subjects. If at any stage in the process the data raise significant concerns about safety or effectiveness, the FDA may request additional information or halt ongoing clinical studies. If all three phases of clinical trials are successful, the sponsor may submit a Biologics License Application (“BLA”), which is a request for permission to introduce a biologic product into interstate commerce. The FDA

reviews the BLA and provides a final response letter to the sponsor, often requiring further clinical trials prior to final approval and licensure.

21. Each year, the Center for Disease Control (“CDC”)’s Advisory Committee on Immunizations Practices (“ACIP”) publishes immunization schedules recommended for pediatric and adolescent persons living in the United States. The schedules have been approved by the American Academy of Pediatrics, the American Academy of Family Physicians, and the American College of Obstetricians and Gynecologists.

22. The current version of the schedule requires the following 15 vaccinations, which protect against 16 diseases, for all people under 18 years of age: (1) hepatitis B; (2) rotavirus; (3) diphtheria, tetanus, and acellular pertussis (“DTaP”); (4) tetanus, diphtheria, and acellular pertussis booster (“Tdap”); (5) *haemophilus influenza* type b (“Hib”); (6) pneumococcal conjugate; (7) inactivated poliovirus (“IPV”); (8) influenza; (9) measles, mumps, and rubella (“MMR”); (10) varicella virus; (11) hepatitis A; (12) meningococcal disease; (13) human papillomavirus (“HPV”); (14) meningococcal B; and (15) pneumococcal polysaccharide.

C. The Sale of Vaccines in the United States

23. In the United States, pediatric vaccines are sold separately to the public sector and the private sector. In the public sector, federal government agencies such as the Veterans Administration and the Department of Defense purchase vaccines under the Federal Supply Schedule (“FSS”). In addition, the CDC purchases vaccines based on prices negotiated by the U.S. Department of Health and Human Services under the Vaccines for Children (“VFC”) program. The VFC program distributes these vaccines at no charge to state health departments and certain public health agencies for distribution to physicians’ offices and public health clinics registered as VFC providers where they are used to vaccinate eligible children based on inability

to pay. The pricing obtained under the FSS and the VFC program is available only to specified government entities and is not offered to the private sector.

24. In the private sector, physician practices and hospitals purchase vaccines directly from manufacturers such as Merck or from wholesalers. Most physicians, physician practices, and hospitals purchase their vaccines pursuant to contracts negotiated by Physician Buying Groups (“PBGs”) or other similar group purchasing organizations (“GPOs”). Those entities are explained further below.

VI. BACKGROUND ON ROTAVIRUS VACCINES

25. Rotavirus is the leading cause of severe acute gastroenteritis (vomiting and severe diarrhea) among infants and young children worldwide. The disease can be severe, leading to dehydration and death. Before rotavirus vaccines were prevalent, rotavirus disease was a common and serious health problem for children in the United States, with nearly all children in the United States experiencing at least one rotavirus infection before their fifth birthday. Every year before the vaccine was available, more than 200,000 children in the United States had to go to the emergency room, 55,000 to 70,000 had to be hospitalized, and up to 60 died.

26. The first vaccine for rotavirus, RotaShield, was licensed by Wyeth Pharmaceuticals and recommended by the CDC for routine childhood immunization in 1998. Wyeth Pharmaceuticals, however, withdrew the vaccine in 1999 due to safety concerns. Scientists associated the vaccine with a rare intestinal problem called intussusception, a potentially fatal telescoping of part of the bowel.

27. Merck was developing its RotaTeq vaccine while RotaShield was on the market. RotaTeq is a pentavalent vaccine; meaning that it protects patients against five rotavirus strains: G1, G2, G3, G4 and P1. It is created by combining human rotavirus genes with WC3 cow virus.

It is administered in three oral doses that are provided as a ready-to-use liquid. The vaccine was created by Dr. H. Fred Clark of the Wistar Institute of the University of Pennsylvania and Dr. Paul Offit, Chief of Infectious Diseases at the Children's Hospital of Philadelphia ("CHOP"). From 1992 to 1993, Merck licensed the RotaTeq vaccine from CHOP and initiated an efficacy trial, with Drs. Clark and Offit as primary investigators. This trial led to a blinded, randomized, placebo-controlled proof-of-concept trial in 439 infants aged 2-6 months old, conducted between 1993 and 1994.

28. After Wyeth withdrew its RotaShield vaccine in 1999, Merck accelerated its testing. In March 2001, Merck began a double-blind, randomized, placebo-controlled "Rotavirus Efficacy and Safety Trial" ("REST trial"), which was believed to be large enough to conclusively demonstrate the efficacy of RotaTeq and to rule out increased intussusception risk. The REST trial tested RotaTeq on 68,000 infants administered at 2-3 months followed by two subsequent doses, each 1-2 months after the last. With the successful results, RotaTeq was licensed by the FDA in February 2006. At the time, Merck was the only manufacturer to sell a rotavirus vaccine in the United States. Like many of Merck's vaccines, it is routinely administered to infants and young children as part of a regular vaccine schedule recommended by the CDC.

29. GSK's Rotarix was developed by Dr. Richard Ward and Dr. David Bernstein at Cincinnati Children's Hospital Medical Center in the early 1990s. Rotarix is an oral live attenuated human vaccine administered in two doses and is provided as a powder that is reconstituted before administration. Unlike RotaShield or Merck's RotaTeq, Rotarix is a single strain or monovalent vaccine, which means it specifically protects against one strain of rotavirus, the G1 strain, which is the strain responsible for the majority of infections in the United States,

and induces some cross-protections against other less-common strains (G3, G4, and G9).

Rotarix is also unique among other rotavirus vaccine candidates in being a human rather than a rhesus or bovine reassortant virus.

30. In 1995, Cincinnati Children's Hospital entered a licensing agreement with the Virus Research Institute, which merged with T Cell Sciences in August 1998 to form Avant Immunotherapeutics. Avant funded a Phase II clinical trial of Rotarix from August 1997 to June 1998 with Dr. Bernstein, now a consultant to Avant and Cincinnati Children's Hospital researcher, as the trial's principal investigator. This trial proved successful and there were few adverse events in the children tested. Avant completed a 2-year extension in May 2000 which showed that effectiveness remained after two years from inoculation. GSK completed 1/11 bridging and Phase II trials in 2002. It then initiated a Phase III trial of 63,000 children aged 6 weeks to 6 months in the third quarter of 2003. The Phase III trial was billed by GlaxoSmithKline Biologicals as the largest infant vaccine trial ever conducted. Rotarix was approved by the FDA in April 2008 for sale in the United States.

31. Revised ACIP recommendations for the use of rotavirus vaccine were published in February 2009. Because of similar estimates of efficacy and safety, neither The Advisory Committee on Immunization Practices (ACIP) nor the Academies of Pediatrics or Family Physicians state a preference for one vaccine over the other. In addition, ACIP recommends that the rotavirus vaccine series be completed with the same product whenever possible. In other words, if a patient begins the series with RotaTeq, it should complete that series with RotaTeq and should not switch to Rotarix, and vice versa.

32. Merck and GSK are the only companies that market a rotavirus vaccine in the United States. But despite competition from Rotarix – a product that the CDC has stated is just

as effective as RotaTeq in preventing rotavirus infection – Merck continues to dominate the Rotavirus Vaccine Market in the United States, currently enjoying over 70% market share.

VII. THE VACCINES INDUSTRY AND ITS RELEVANT MARKETS

A. Vaccine Manufacturers

33. The sales of vaccines are large and rapidly expanding. In 2005, global vaccine sales generated approximately \$10 billion in revenue, and that number more than quadrupled to approximately \$41 billion in 2015. Vaccines are commonly segmented into two target segments: adult and pediatric.

34. In recent decades, vaccine markets in the United States have become highly concentrated. In 1967, 26 different companies held vaccine licenses in the United States, but by 2002, that number had dropped to 12. In 2008, only four companies sold pediatric vaccines in the United States: Merck, GSK, Sanofi Pasteur Inc. (“Sanofi”), and Pfizer (“Pfizer”). Novartis began selling one pediatric vaccine in the United States in February 2010 but sold its pediatric vaccine business to GSK in March of 2015. After Novartis sold its vaccine business to GSK, there were again only four manufacturers in the United States selling the pediatric vaccines recommended on the ACIP schedule. The pediatric vaccine marketplace is highly concentrated among Merck, Sanofi, GSK, and Pfizer.

35. In addition to this concentration, two of the largest vaccines manufacturers, Merck and Sanofi, have reached agreements to cooperate in various ways in their sales of vaccines. Since 1994, Merck and Sanofi have operated a joint venture, Sanofi Pasteur MSD, which markets both companies’ lines of vaccines in Europe. In the United States, because Merck and Sanofi have complementary vaccine lines and similar bundling programs, most PBGs provide access to, monitor, and enforce loyalty to both companies’ complementary bundles.

36. The following chart indicates the pediatric vaccine products manufactured by Merck and its rivals in 2011:

	Sanofi	GSK	Merck	Novartis	Pfizer ⁶
Hepatitis B		Engerix B Twinrix* ⁷ Pediarix*	Recombivax Comvax* ³		
DTaP	Daptacel Pentacel*	Infanrix Kinirix* Pediarix*			
Tdap	Adacel	Boostrix			
Polio (IPV)	IPOL Pentacel*	Kinrix* Pediarix			
Streptococcus			Pneumovax ⁴		Prevnar
Hib	ActHIB	Hiberix ¹	PedvaxHIB ³ Comvax* ³		
Rotavirus		Rotarix	RotaTeq		
MMR			MMR II		
Varicella			Varivax		
Hepatitis A		Havrix Twinrix* ⁷	Vaqta		
Meningitis (MCV4)	Menactra Menomune ²			Menevo ⁵	
HPV		Cervarix	Gardasil		

* Combination vaccine.

¹ Limited use. Hib is administered as a three or four dose series. GSK's Hiberix was licensed in August 2009 but is only licensed for the final dose of the three or four dose Hib series.

² Not widely used.

³ Subject of recall in 2007. Merck had limited supplies available for sale from 2007 through 2010.

⁴ Licensed in 2011.

⁵ Licensed in February 2010. Acquired by GSK in 2015.

⁶ Prevnar was originally developed and manufactured by Wyeth. Pfizer acquired Wyeth in 2009.

⁷ Twinrix can only be used for adults and therefore is not functionally interchangeable with pediatric Hepatitis A vaccines.

B. Relevant Product Markets

37. Merck's bundled loyalty contracts effectively leveraged its market power in a number of pediatric vaccine markets to maintain its monopoly power in the Rotavirus Vaccine

Market. To the extent that plaintiff must prove monopoly power circumstantially by first defining a relevant product market, the following seven product markets are potentially relevant to plaintiff's antitrust claims.

1. Rotavirus Vaccine Market

38. The sale of rotavirus vaccines in the United States is a relevant product market.
39. The Rotavirus Vaccine Market contains all FDA-approved vaccines that inoculate against rotavirus.
40. In February 2006, the FDA licensed RotaTeq, a rotavirus vaccine marketed by Merck, for sale in the United States. RotaTeq is administered in a three-dose series, with doses administered at ages two, four, and six months.
41. In April 2008, the FDA licensed Rotarix, a rotavirus vaccine marketed by GSK, for sale in the United States. Rotarix is administered in a two-dose series, with doses administered at ages two and four months.
42. Revised ACIP recommendations for the use of rotavirus vaccine were published in February 2009. Because of similar estimates of efficacy and safety, neither ACIP nor the Academies of Pediatrics or Family Physicians state a preference for one vaccine over the other.
43. The ACIP pediatric immunization schedule recommends rotavirus vaccine as a two- or three-dose series, with the first dose at two months, the second at four months, and the third at six months (if RotaTeq is used).
44. There are no reasonably available substitutes for rotavirus vaccines.
45. Prior to 2008, Merck had 100% market share in the Rotavirus Vaccine Market. After GSK entered the market in 2008, Merck's market share dropped slightly, but on

information and belief remained above 68% through the present day. In 2016, Merck's market share was 73%.

46. At all relevant times, Merck possessed monopoly power in the Rotavirus Vaccine Market.

47. A small but significant, non-transitory increase above competitive prices for rotavirus vaccines would not cause a significant loss of sales such as to make the increase unprofitable.

48. Products in the Rotavirus Vaccine Market do not exhibit significant, positive cross-elasticity of demand with respect to price with products that are not in the Rotavirus Vaccine Market.

49. Merck has sold its rotavirus vaccine at supracompetitive prices well in excess of marginal costs and in excess of the competitive price, and has enjoyed high profit margins.

2. Hepatitis A Pediatric Vaccine Market

50. The sale of pediatric hepatitis A vaccines in the United States is a relevant product market.

51. The hepatitis A vaccine inoculates against the hepatitis A virus, which causes liver disease.

52. The Hepatitis A Pediatric Vaccine Market contains all FDA-approved vaccines for use in children from birth to 18 years of age that inoculate against the hepatitis A virus.

53. The ACIP pediatric vaccine schedule recommends that children get a two-dose series of hepatitis A vaccine at ages twelve through twenty-three months and a second dose six to eighteen months after the first dose.

54. There are two pediatric hepatitis A vaccines available in the United States: Havrix and Vaqta. GSK sells Havrix and Merck sells Vaqta. GSK also sells Twinrix, a combination hepatitis A and hepatitis B vaccine, but it can only be used for adults and therefore is not functionally interchangeable with pediatric hepatitis A vaccines.

55. There are no reasonably available substitutes for pediatric hepatitis A vaccines.

56. Products in the Hepatitis A Pediatric Vaccine Market do not exhibit significant, positive cross-elasticity of demand with respect to price with products that are not in the Hepatitis A Pediatric Vaccine Market.

57. A small but significant, non-transitory increase above competitive prices for hepatitis A pediatric vaccines would not cause a significant loss of sales such as to make the increase unprofitable.

3. Hepatitis B Pediatric Vaccine Market

58. The sale of pediatric hepatitis B vaccines in the United States is a relevant product market.

59. Hepatitis B vaccines inoculate against the hepatitis B virus, which can cause lifelong infection, cirrhosis (scarring) of the liver, liver cancer, and liver failure.

60. The Hepatitis B Pediatric Vaccine Market contains all FDA-approved vaccines that inoculate against the hepatitis B virus and are approved for use in children aged 0 to 18.

61. The ACIP pediatric vaccine schedule recommends that children get three doses of Hepatitis B vaccine: at birth, between one and two months, and between six and eighteen months.

62. There are currently four different hepatitis B vaccines available in the United States. GSK sells Engerix B and Pediarix, a combination vaccine that includes pediatric hepatitis

B vaccine. Merck sells Recombivax HB and sold Comvax until it was discontinued. GSK also sells Twinrix, a combination hepatitis A and hepatitis B vaccine, but it can only be used for adults and therefore is not functionally interchangeable with pediatric hepatitis B vaccines.

63. There are no reasonably available substitutes for pediatric hepatitis B vaccines.

64. Products in the Hepatitis B Pediatric Vaccine Market do not exhibit significant, positive cross-elasticity of demand with respect to price with products that are not in the Hepatitis B Pediatric Vaccine Market.

65. A small but significant, non-transitory increase above competitive prices for pediatric hepatitis B vaccines would not cause a significant loss of sales such as to make the increase unprofitable.

4. *Haemophilus Influenzae Type B (“Hib”)* Vaccine Market

66. The sale of *haemophilus influenza* type b (“Hib”) vaccines in the United States is a relevant product market.

67. Hib vaccines inoculate against a type of bacteria called *haemophilus influenzae* type b, which can cause meningitis (an infection of the covering of the brain and spinal cord), pneumonia (lung infection), and epiglottitis (a severe throat infection).

68. The Hib Vaccine Market contains all FDA-approved vaccines that inoculate against *haemophilus influenzae* type b.

69. The ACIP pediatric vaccine schedule recommends that children get three or four doses of Hib vaccine at two, four, and six months (depending on the brand of vaccine used), and a booster dose between twelve and fifteen months.

70. There are currently five different Hib vaccines available in the United States. The five vaccines are ActHIB, Hiberix, PedvaxHIB, Pentacel, and Menhibrix. GSK sells Hiberix and

Menhibrix, the latter of which is only approved by ACIP for the last dose of the Hib series.

Merck sells PedvaxHIB. Sanofi sells ActHIB and Pentacel. Merck also sold Comvax until March 31, 2014, at which point it was discontinued.

71. There are no reasonably available substitutes for Hib vaccines.

72. Products in the Hib Vaccine Market do not exhibit significant, positive cross-elasticity of demand with respect to price with products that are not in the Hib Vaccine Market.

73. A small but significant, non-transitory increase above competitive prices for Hib vaccines would not cause a significant loss of sales such as to make the increase unprofitable.

74. Sanofi has held a dominant share of the Hib Vaccine Market throughout the relevant period. Merck suspended production of both of its Hib vaccines from 2007 through 2009 because inspections of its facilities revealed contamination by foreign bacteria. Between 2010 and 2013, Merck's market share in the Hib Vaccine Market (including Pedvax HIB and Comvax) increased steadily from about 8% to 18%.

5. Measles, Mumps, and Rubella (“MMR”) Vaccine Market

75. The sale of MMR vaccines in the United States is a relevant product market.

76. The MMR Vaccine Market contains all FDA-approved vaccines that inoculate against the measles (rubeola), mumps, and rubella (German measles) viruses.

77. The ACIP pediatric vaccine schedule recommends that children get a two-dose series of MMR vaccine at ages twelve through fifteen months and at ages four through six years.

78. There are two MMR vaccines available in the United States: MMRII and ProQuad is a combination vaccine that also inoculates against Varicella. Merck sells both MMRII and ProQuad.

79. There are no reasonably available substitutes for MMR vaccines.

80. Products in the MMR Vaccine Market do not exhibit significant, positive cross-elasticity of demand with respect to price with products that are not in the MMR Vaccine Market.

81. A small but significant, non-transitory increase above competitive prices for MMR vaccines would not cause a significant loss of sales such as to make the increase unprofitable.

82. Merck is the sole provider of MMR vaccines in the United States and has been the sole provider for the relevant period.

6. Varicella Vaccine Market

83. The sale of Varicella vaccines in the United States is a relevant product market.

84. The Varicella Vaccine Market contains all FDA-approved vaccines that inoculate against the varicella virus, commonly known as chicken pox.

85. The ACIP pediatric vaccine schedule recommends that children get a two-dose series of varicella vaccine at ages twelve through fifteen months and at ages four through six years.

86. There are two Varicella vaccines available in the United States: Varivax and ProQuad. ProQuad is a combination vaccine that also inoculates against MMR. Merck sells both Varivax and ProQuad.

87. There are no reasonably available substitutes for Varicella vaccines.

88. Products in the Varicella Vaccine Market do not exhibit significant, positive cross-elasticity of demand with respect to price with products that are not in the Varicella Vaccine Market.

89. A small but significant, non-transitory increase above competitive prices for Varicella vaccines would not cause a significant loss of sales such as to make the increase unprofitable.

90. Merck is the sole provider of Varicella vaccines in the United States and has been the sole provider for the relevant period.

7. HPV Vaccine Market

91. The sale of HPV vaccines in the United States is a relevant product market.

92. The HPV vaccine inoculates against human papillomavirus infection.

93. The HPV Vaccine Market contains all FDA-approved vaccines that inoculate against human papillomavirus, which can cause a variety of cancers, such as cervical cancer in women, and genital warts in both men and women.

94. The ACIP pediatric vaccine schedule recommends that adolescents receive a three-dose series of HPV vaccines on a schedule of 0, 1 to 2, and 6 months, to all adolescents aged 11 through 12 years.

95. There are two HPV vaccines available in the United States: Gardasil and Cervarix. Merck sells Gardasil, which was licensed in June 2006, and is one of its most profitable products, grossing over \$1.9 billion in 2015. GSK sells Cervarix, which was licensed by the FDA in 2009.

96. There are no reasonably available substitutes for HPV vaccines.

97. Products in the HPV Vaccine Market do not exhibit significant, positive cross-elasticity of demand with respect to price with products that are not in the HPV Vaccine Market.

98. A small but significant, non-transitory increase to competitive prices for HPV vaccines would not cause a significant loss of sales such as to make the increase unprofitable.

99. Merck was the sole provider of HPV vaccines in the United States until 2009, and has maintained a dominant share of the HPV Vaccine Market since then and throughout the relevant period. In 2015, Merck had a 99.7% share in the HPV Vaccine Market, and in 2016, GSK exited the market, restoring Merck's 100% market share.

C. The Relevant Geographic Market is the United States

100. The relevant geographic market for the vaccine product markets described above is the United States. Vaccines are subject to a complex regulatory framework under which drug approval in the United States is governed by the FDA. In addition, prices vary widely inside and outside of the United States due to different national regulatory regimes.

D. Barriers to Entry

101. United States vaccines markets, including pediatric vaccine markets, are characterized by high barriers to entry including substantial upfront fixed costs, intellectual property protection, and substantial regulatory hurdles. As one academic study notes, "threat of new entrants in this market is seemingly low as the barriers to entry when developing biological products like vaccines are quite high."¹

102. Vaccine manufacturing is characterized by high fixed costs and economies of scale. The processes used to manufacture vaccines often use proprietary cell lines and virus stains that are difficult to duplicate. In addition, a manufacturer cannot bring a vaccine to market in the United States without obtaining an FDA license through the regulatory process for biologics. The ANDA process is not available for biologics in the United States, and the

¹ Kevin W. Caves & Hal J. Singer, *Bundles in the Pharmaceutical Industry: A Case Study of Pediatric Vaccines* at 14 (2011), available at <https://www.law.berkeley.edu/wp-content/uploads/2015/04/Caves-Singer-Bundles-in-the-Pharmaceutical-Industry-2011.pdf> (quoting Frost & Sullivan, Global Vaccines Market, Dec. 7, 2009, at 4).

approval process for biosimilar products requires new entrants to perform costly clinical studies in order to obtain FDA approval. Those time-consuming and costly clinical trials may or may not result in licensing for a new vaccine. As a result, fixed costs are high in United States vaccine markets and barriers to entry make it difficult for new companies to develop, license, and bring a new vaccine to market.

103. One academic study has indicated that the cost of developing a new vaccine is as high as \$1 billion.² Another widely-cited study concluded that R&D costs for “new molecular entities” representing truly new drugs in 200 was over \$800 million.³ A more conservative study estimated that it cost GSK between \$172 million and \$551 million to develop and license Rotarix.⁴

104. In addition to large upfront costs for R&D and capital expenditures necessary to manufacture a vaccine, there are substantial economies of scale in vaccine manufacturing. Thus, established firms with larger output can have lower per-unit costs than new entrants with lower volumes due to the ability to spread such costs as plant administration, quality control, laboratory operation, health and safety, and utilities over a higher volume of output.

105. The existence of high entry barriers is also indicated by the lack of entry. For example, Merck has yet to experience any competition in the MMR vaccine market since the introduction of its MMR vaccines more than forty years ago.

² See, e.g., Plotkin, Orenstein & Offit, *Vaccines*, 35 (6th ed. 2013).

³ J.A. DiMasi et al., *The price of innovation: new estimates of drug development costs*, *Journal of Health Economics* (2003).

⁴ Donald W. Light et al., *Estimated research and development costs of rotavirus vaccines*, *Vaccine* (Nov. 2009).

VIII. MERCK HAS WILLFULLY MAINTAINED ITS MONOPOLY POWER IN THE ROTAVIRUS VACCINE MARKET

A. Merck Has Monopoly Power in the Rotavirus Vaccine Market and Others

106. Merck has had monopoly power in the following markets throughout the relevant period and up to the present: the Rotavirus Vaccine Market, the MMR Vaccine Market, the Varicella Vaccine Market, and the HPV Vaccine Market. In addition, at certain times during the relevant period, Merck has had market power in the Hepatitis B Pediatric Vaccine Market and the Hepatitis A Pediatric Vaccine Market. Merck has had the power to exclude competitors and price above competitive levels in each of these markets during the relevant period.

107. From the time it received FDA approval to sell RotaTeq in February 2006 until GSK entered the market in 2008, Merck had a 100% monopoly in the Rotavirus Vaccine Market in the United States. Merck also had a 100% monopoly in the MMR, Vaicella, and HPV Vaccine Markets, as well as a substantial share in the Hepatitis A and Hepatitis B Pediatric Vaccine Markets.

108. In 2008, GSK planned to bring a competing rotavirus vaccine, Rotarix, to market. Rotarix was approved by the FDA in April 2008 for sale in the United States. At the time, GSK sold competing hepatitis A, hepatitis B, and Hib pediatric vaccines, but did not sell an MMR vaccine, a Varicella vaccine, or an HPV vaccine (until Cervarix was introduced later).

109. Merck responded to this competition from GSK not by lowering the price of RotaTeq as economics would predict, but instead by using bundled loyalty contracts to foreclose competition from GSK. Upon information and belief, these contracts foreclose competition in more than 40% of the relevant market, and they have allowed Merck to leverage its monopoly power in multiple pediatric vaccine markets to maintain its monopoly power in the

Rotavirus Vaccine Market. This scheme effectively divided the Rotavirus Vaccine Market by making it more profitable for GSK to price at supra-competitive price levels, to maximize its revenues in the portion of the market not foreclosed by the Merck Bundle, than to charge the very lower prices that would be required to compete against Merck in the portion of the market subject to the Merck Bundle.

B. Merck Entered Into a Series of Exclusionary Bundled Loyalty Contracts

110. Merck was the sole seller of pediatric rotavirus vaccine in the United States from 2006 until GSK received to sell Rotarix in 2008. In response to this competitive threat from GSK in the Rotavirus Vaccine Market, Merck added its exclusionary RotaTeq Bundled Loyalty Condition to the Merck Bundle, thereby bundling RotaTeq with its other pediatric vaccines.

111. Under these contracts, customers must agree to purchase all or nearly all of their rotavirus vaccines from Merck, and thus forego purchasing Rotarix from GSK. Customers who do not abide by this loyalty requirement pay disloyalty penalties not only on their purchases of RotaTeq, but also on their purchases of hepatitis A, hepatitis B, Hib, Varicella, MMR, and HPV vaccines from Merck. Thus, customers who instead attempt to purchase Rotarix from GSK are penalized by being forced to pay substantially higher prices for all of the vaccines in the Merck Bundle, from 2% to 58% higher, depending on the vaccine.

112. For example, in 2008, a letter sent from Merck to Atlantic Health Partners amended their contract so that it required 80% market share loyalty on Merck's rotavirus vaccine in order to avoid hundled penalty prices on Merck's MMR II, Pneumovax23, Proqud, Varivax, Gardasil, and Zostavax vaccines.

113. Although physicians, practices, and hospitals purchase vaccines directly from manufacturers, most do so pursuant to contracts negotiated by PBGs or other similar GPOs (collectively referred to as “buying groups”).

114. PBGs are typically privately held, for-profit entities, with membership consisting of thousands of family practices, pediatricians, and other independent medical practices. PBGs perform various services on behalf of their members, including coordinating and aggregating member purchases of vaccines and other healthcare supplies through group purchasing contracts with major vaccine manufacturers and medical supply distributors. Because PBGs seldom charge membership dues or participation fees, most or all of their compensation typically comes in the form of rebates and administrative fees paid by vendors (based on PBG members’ aggregate expenditures). To qualify for non-penalty vaccine prices, PBGs typically require that participating practices agree to contractual terms that typically include manufacturer exclusivity. Manufacturers grant rebates to PBGs based on their success in enrolling practices and aggregating purchase volumes. The receipt of these administrative fees and rebates is usually dependent on the PBG’s compliance with the loyalty terms contained in their contracts, and thus provides a strong incentive for the PBG to ensure its members maintain loyalty to the manufacturer. PBGs may share some portion of these rebates with their members, and may also keep some portion for themselves.

115. Continuing to the present, Merck has imposed its bundled loyalty conditions through a series of exclusionary contracts with PBGs and other GPOs, and by extension, the providers and institutions that are members of these groups. On information and belief, before GSK entered the Rotavirus Vaccine Market, Merck already had agreements in place with buying groups that provided buyers certain contract prices for all vaccines in Merck’s portfolio if (and

only if) the buyers committed to buying all or nearly all of their hepatitis A and hepatitis B and vaccines from Merck. Notably, before GSK received approval for Rotarix, Merck's contract prices were not contingent upon loyalty to RotaTeq, a vaccine for which Merck faced no competition, unlike with the vaccines for hepatitis A, hepatitis B, and Hib. In response to GSK's entry into the Rotavirus Vaccine Market, however, Merck added the RotaTeq Bundled Loyalty Condition to its contracts. This condition required the purchaser either to maintain a high RotaTeq share (such as 90% or 100%) of its total rotavirus vaccine purchases, or to be penalized by losing contract prices on all of Merck's pediatric vaccines and being forced to pay the higher "list" prices for the Merck vaccines. Merck has continued to sign additional contracts and contract amendments through the present that include the RotaTeq Bundled Loyalty Condition.

116. After the addition of the RotaTeq Bundled Loyalty Condition, receipt of bundled contract prices for Merck's portfolio of pediatric vaccines became contingent on maintaining loyalty to RotaTeq. Buying groups generate revenue primarily through the administrative fees and rebates paid by manufacturers as a percent of the buying group's total purchases of the manufacturer's products. When Merck added the RotaTeq Bundled Loyalty Condition to its contracts, however, it also made receipt of these rebates contingent upon the PBG or GPO maintaining member loyalty to RotaTeq, whereas before the RotaTeq Bundled Loyalty Condition was added, loyalty was only required on Merck's other vaccines. For example, if a buying group's members failed to meet their collective loyalty requirement on RotaTeq, that buying group could lose its administrative fee earned on *all* of its members' pediatric vaccine purchases from Merck, not just those earned on RotaTeq purchases.

117. Because Merck and Sanofi manufacture vaccines in complementary rather than competing markets (the only exception being the Hib Vaccine Market, which Merck withdrew

from for much of the relevant period), many of Merck's bundled loyalty contracts allow customers to purchase Sanofi's complementary vaccines, but *forbid* the customer from purchasing competing vaccines from GSK.

118. The following summarizes some of PBGs and GPOs that have exclusionary contracts with Merck that contain bundled loyalty provisions requiring *de facto* exclusivity or near exclusivity on Merck's rotavirus vaccines:

Atlantic Health Partners

119. Atlantic Health Partners is a leading PBG specializing in vaccines. AHP has negotiated exclusive vaccine purchasing contracts with both Merck and Sanofi. Participating physicians' practices agree to exclusivity on rotavirus vaccines (as well as others) in exchange for avoiding penalties on its prices for Merck's vaccine portfolio.

CCPA Purchasing Partners

120. CCPA Purchasing Partners offers a "Merck Contract Only" that requires physician practices to agree to "purchase Merck's Hepatitis A (Vaqta), Hepatitis B (Recombivax HB), MMR (M-M-R II), Varicella (Varivax), HPV (Gardasil/Gardasil9), Rotavirus (RotaTeq), HIB (PedVax HIB) and Pneumococcal (Pneumovax23) vaccine products as needed. By selecting this option, [the] practice agrees not to purchase GlaxoSmithKline's Havrix, Engerix-B, Twinrix, Hiberix, Ceravix, Rotarix, and Pediarix products, and/or any other vaccine product that competes with the Merck products noted above. It is understood that failure to comply with these compliance terms may result in price increases, loss of administrative awards, and termination of [the] practice from CCPAPP's Merck contract."⁵

⁵ CCPA Purchasing Partners Vaccine Contracting & Compliance Form, *available at* https://www.ccapp.org/assets/1/7/7._2016_Vaccine_Contracting_and_Compliance_Form_Fillable1.pdf.

121. The CCPA Purchasing Partners Vaccine Contracting Guide further explains that “[i]f your practice is participating *only* in the Merck agreement (and not the Sanofi Pasteur agreement with CCPAPP), your practice must agree to purchase as needed: Merck’s Hepatitis A (Vaqta), Hepatitis B (Recombivax HB), Measles, Mumps and Rubella Virus (M-M-R II), Varicella (Varivax), HPV (Gardasil/Gardasil9), Rotavirus (RotaTeq), HIB (PedvaxHib) and Pneumococcal (Pneumovax 23) vaccine products. By selecting this option, your practice agrees not to purchase GlaxoSmithKline’s Hepatitis A (Harvix), Hepatitis B (Engerix-B), Hepatitis A-Hepatitis B combination (Twinrix), HPV (Cervarix), Rotavirus (Rotarix), HIB (Hiberix), and Polio-DTap-Hepatitis B combination (Pediarix) products, and/or any other vaccine product that competes with the Merck products noted above.”⁶

CASA Physicians Alliance

122. CASA Physicians Alliance offered its members a Merck contract that included “Core Products,” which “should be purchased through Merck or one of the Prime Distributors approved by Merck in lieu of equivalent vaccines from any other vendors.” The Core Products included RotaTeq.⁷ If CASA members met the performance requirements on the core products, it provided penalty-free prices on the full-line of Merck vaccines, including Gardasil, MMRII, Proquad, Varivax, and RotaTeq.⁸

⁶ CCPA Purchasing Partners Vaccine Contracting Guide, *available at* https://www ccpapp org/assets/1/7/CCPAPP_Vaccine_Contracting_Guide_2016.pdf.

⁷ CASA Physicians Alliance Participation Agreement, *available at* <http://www.casaalliance.net/download/AAADM%20-B%20PARTICIPATION%20AGREEMENT%20CURRENT%20032917.pdf?inline>.

⁸ Discount vaccines available to CASA Physician GPO members, *available at* <http://www.casaalliance.net/merck>.

CNHN Vaccine Group

123. CNHN Vaccine Group offers a vaccine group purchase program with Merck.

CNHN Vaccine Group's Purchase Information explains that:

To receive our CNHN contract pricing, members agree to purchase Sanofi or Merck products where competing vaccines exist. In return our members receive the region's best pricing on the full portfolio of Sanofi and Merck vaccines. Occasionally, a competing product may briefly be lower-priced; however, CNHN practices realize significant savings when you calculate the total vaccine purchases made annually by our practices CNHN members cannot selectively participate in CNHN vaccine contract for some vaccine and simultaneously purchase competing products off contract. CNHN pricing is tiered to contract performance. The closer we come to 100% ordering compliance, the better we all do. CNHN does not endorse practices ordering small amounts of competing products. Doing so violates our contract terms and jeopardizes group pricing for all our participating CNHN members.⁹

Main Street Vaccines

124. Merck's agreement with the Main Street Vaccines PBG "requires the preferential use of: RECOMBIVAX, VAQTA, RotaTeq, Gardasil/Gardasil 9, [and] ZOSTAVAX."¹⁰

According to the Main Street Vaccine's web page describing the agreement, "Members can use any combination of Merck vaccines *but may not use competing vaccines from other manufacturers.*"¹¹

Medical Practice Purchasing Group

⁹ CNHN Vaccine Group Purchase Information, available at <https://childrensnational.org/-/media/cnhs-site/files/healthcare-providers/cnhn/vaccinecontract.pdf?la=en&hash=9EE24D92C0B1D5A8CB84267B688E0B6205C88770>.

¹⁰ The Main Street Vaccines/Merck Agreement, available at <http://www.mainstreetvacs.com/merck-2/>.

¹¹ *Id.* (emphasis added).

125. Medical Practice Purchasing Group (“MPPG”) offers special pricing and additional rebates to physician members. Under the MPPG contract, members agree “to use the full portfolio of vaccine-related pharmaceutical products covered under the MPPG contracts in the volume and ratios contemplated by the recommended immunization schedules.”¹² MPPG pays rebates, which it calls “loyalty payments”, to members “since our group pricing is based on brand loyalty. Members purchasing our contracted partners’ products and not their competitors’ can earn eligibility for these awards.”¹³ MPPG’s FAQs also remind members that “[i]f you are interested in receiving the vaccine discounts, keep in mind our group pricing is based on our members purchasing Merck and/or Sanofi Pasteur vaccines and not their competitors’. Our compliance rates are exceptionally high and we appreciate our members’ dedication to the group’s benefit.”¹⁴

National Discount Vaccine Alliance

126. National Discount Vaccine Alliance’s (“NDVA”) 2009 Membership Agreement for Merck vaccines required that NDVA and its members maintain a minimum level of 90% market share on RotaTeq and other Merck pediatric vaccines, or “be considered non-compliant and subject to immediate removal from the contract. This will be monitored no less than quarterly.”¹⁵ If a medical practice is non-compliant, it risks having penalties imposed as follows:

¹² MPPG Member Agreement, available at http://www.mppg.net/wp-content/uploads/2016/04/April-2016-participation_agreement_.pdf.

¹³ FAQs, available at <http://www.mppg.net/membership/faqs/>.

¹⁴ *Id.*

¹⁵ Membership Agreement, available at <http://nebula.wsimg.com/79e43736b37bf4e496ee7e8d092d1404?AccessKeyId=178AB8FC86C5F686B8A4&disposition=0&alloworigin=1>.

34% on purchases of Recombivax, 29% on purchases of Vacta, 6% on purchases of RotaTeq, 3% on purchases of ProQuad, MMR, and Varivax, and 2% on purchases of Pneumovax 23, Zostavax and Gardasil.¹⁶

Unified Physicians Society

127. Unified Physicians Society (“UPS”) is a for-profit PBG that has thousands of pediatrician members. UPS has negotiated market share agreements with Merck and Sanofi. According to UPS’ FAQs, “[i]n order to receive the highest discounts, our members have chosen to utilize these product lines exclusively. The only vaccine our members do not purchase on contract is Pneumococcal Conjugate Vaccine for Pediatric Use, which is not available through Sanofi Pasteur or Merck.”¹⁷

PedsPal

128. PedsPal, a GPO, has an agreement with Merck that is similar to CASA Physicians Alliance’s agreement with Merck.¹⁸

River Valley Pediatricians, Inc.

129. River Valley Pediatricians, Inc. (“RVPI”) is a group purchasing organization that serves 44 pediatric practices in greater Cincinnati, northern Kentucky, and southeast Indiana. It allows members to avoid penalties on their pricing on RotaTeq and other Merck vaccines in exchange for loyalty. RVPI’s membership application “requires total purchasing support of those contracts that include ‘loyalty/compliance’ discount clauses that have been approved by the

¹⁶ *Id.*

¹⁷ FAQs available at <http://www.unifiedphysiciansociety.com/index.php/faqs>.

¹⁸ PedsPal Group Purchasing Program, available at <http://www.pedspal.org/SiteCollectionDocuments/Join/PEDSPAL-JoinNow.pdf>.

RVPI Board. These require achievement by all members collectively of market share purchases equal to or greater than 90% of total product purchases.” The agreement also states that “[f]ailure to comply with these purchasing agreements will result in termination from the agreements.”¹⁹

C. Merck Works With PBGs to Enforce Its Exclusionary Contracts

130. Since 2008 and continuing to the present, Merck has worked together with PBGs to enforce the exclusionary terms in its contracts and to make sure that customers do not buy competing vaccines such as GSK’s Rotarix. Merck enforces the contracts through the threat of higher prices for RotaTeq and other vaccines in the bundle as well as through the threat of withholding administrative fees and rebates from PBGs whose members purchase Rotarix from GSK.

131. For example, CCPA Purchasing Partners’ Vaccine Contracting Guide explains that “failure to meet contract compliance by practices may result in price increases and loss of administrative fees for ALL CCPAPP practices, we do not tolerate non-compliance within our contract terms. CCPAPP will notify your practice of any purchase activity that is not in compliance with our Merck agreement. If the non-compliance continues, we will promptly send written notice via certified mail to your practice informing you of your termination from our contract.”²⁰

132. Similarly, CASA Physicians Alliance’s website explains that it “reviews individual member purchases on a continuous basis to insure individual clinic performance meets

¹⁹ Membership Application.

²⁰ CCPA Purchasing Partners Vaccine Contracting Guide, available at https://www ccpapp org/assets/1/7/CCPAPP_Vaccine_Contracting_Guide_2016 pdf

the participation requirements.”²¹ CNHN Vaccine Group explains that “[t]he closer our group comes to 100% contract purchase compliance, the better the pricing for all. CNHN will remove practices from DNH contracts for failure to comply with contract terms.”²² A “Frequently Asked Questions” document on the Main Street Vaccines website explains that “[w]e get rock bottom prices on Sanofi Pasteur and Merck Vaccines by agreeing to their exclusive use. Main Street Vaccines and its member practices may not use competing vaccines except for explicit reasons of medical necessity or product unavailability.”

133. PBGs also help Merck monitor their members’ compliance with Merck’s bundled loyalty contracts. For example, a question on the Main Street Vaccines “Frequently Asked Questions” page asks “Can you really tell if I am buying vaccines outside the contract?” The answer is “Yes, we can. When that happens you may receive a warning or notice terminating your membership with the loss of all accrued benefits. Periodically, competing manufacturers ‘advise’ members of ways to skirt our agreements and use their products. This is almost always detected and results in removal from our contract(s).”²³ Similarly, Unified Physicians Society’s “Frequently Asked Questions” page explains that “[o]ur contract member purchases are monitored by the manufacturers and our discounts/terms are based on members adhering to these guidelines.”²⁴

²¹ Discount vaccines available to CASA Physician GPO members, *available at* <http://www.casaalliance.net/merck>.

²² Vaccine Group Purchase Programs, *available at* <https://childrensnational.org/healthcare-providers/physician-networks/childrens-national-health-network-cnhn/benefits-of-cnhn-membership/vaccine-group-purchase-programs>.

²³ Caves & Singer, *supra*, n.3 at 25 n.56 (quoting Frequently Asked Questions, <http://www.mainstreetvacs.com/faq.html>).

²⁴ FAQs, *available at* <http://unifiedphysicianssociety.com/index.php/faqs>.

D. Merck's Exclusionary Bundled Loyalty Contracts Have Substantially Foreclosed Competition in the Rotavirus Vaccine Market

134. By requiring their customers to purchase all or nearly all of their rotavirus vaccines from Merck, Merck's bundled contracts substantially foreclosed competition in the Rotavirus Vaccine Market. On information and belief, Merck's bundled contracts have foreclosed competition in greater than 40% of the relevant market.

135. GSK is the only competitor to Merck in the Rotavirus Vaccine Market, having received a license for Rotarix in April 2008 and entered the market shortly thereafter.

136. Because failure to comply with the loyalty conditions on RotaTeq under Merck's contracts can lead to substantial penalties on a portfolio of other vaccines that physicians purchase from Merck (including those that they cannot get from anyone else), the contracts effectively raised the cost of purchasing Rotarix. This is because, even if GSK offered Rotarix at a lower price than RotaTeq, physicians and hospital purchasers would have to weigh that difference against the penalty they would be forced to pay on *all* of their other vaccine purchases from Merck.

137. In order to overcome the incremental pricing penalty that a typical restrained customer would incur due to violating the RotaTeq Bundled Loyalty Condition, GSK would have had to sell Rotarix at such a low price to attract restrained customers that it was instead more profitable to sell at a much higher price, foregoing sales to the restrained customers, but maximizing revenues from customers not subject to the Merck Bundle. For example, assuming a physician practice purchased the ACIP recommended portfolio of pediatric vaccines for each of its patients, Merck's RotaTeq Bundled Loyalty Condition imposed penalties of \$25.91 per rotavirus dose, which represents approximately 40% of Merck's nominal loyal RotaTeq price (\$64.71). This means that GSK would have to price its competing rotavirus vaccine more than

forty percent below Merck's loyal price for RotaTeq in order to counterbalance the penalties the customer would have to pay on Merck's portfolio of vaccines. It had no incentive to do this under the circumstances.

138. One reason GSK had no incentive to offer a more than 40% discount to foreclosed customers is that it could not price discriminate (by at the same time offering smaller or not discounts to unrestrained customers) sufficiently to make this option more profitable than adopting a market-wide high-price strategy. Due to the Merck Bundle, in order to compete for the Merck-loyal customers, GSK's only choice would have been to take a step it had no incentive to take: cut its prices dramatically to *all* of its customers, including those who were *not* subject to the Merck Bundle. Additionally, with respect to public purchasers of vaccines, the VFC program allows states to buy vaccines at the lowest-private sector price. Thus, if GSK attempted to compete for foreclosed customers by offering a deeply discounted price, it would have to charge that price to public customers as well, at a minimum. In this way, Merck's bundled pricing scheme was designed to ensure that GSK's profit maximizing option was *not* to compete with Merck for the foreclosed portion of the market, but rather, to charge high prices market-wide.

139. In addition, GSK could not effectively compete for foreclosed customers by offering a competing bundle, for two reasons.²⁵ First, Merck offered multiple vaccines that GSK did not, including HPV, MMR, and Varicella vaccines. Because these vaccines are required under the ACIP recommendations, very few customers could avoid purchasing these products from Merck, and GSK could offer no substitutable vaccines. Second, because ACIP

²⁵ Although GSK may have used some bundled loyalty discounts of its own, economists have shown that only worsens the anticompetitive effects of the market division.

recommends that patients complete their vaccination schedule using the same brand of vaccine by physician practices and hospitals is incontestable, meaning that the customer cannot, consistent with good medical practice, switch *all* of its purchases to another supplier no matter what price is offered. Thus, the customer would still be forced to pay penalty prices on the remaining Merck vaccines that it could not switch to GSK.

140. As a result, the Merck Bundle reduced GSK's incentive to compete for market share in the Rotavirus Vaccine Market overall by reducing its prices. The Merck Bundle prevented the erosion of Merck's market share and monopoly power, allowing Merck to foreclose a substantial share of the Rotavirus Vaccine Market and maintain high prices. Had Merck not used the Merck Bundle to foreclose competition in the Rotavirus Vaccine Market, GSK would have achieved greater sales at lower prices than it actually did and would have forced Merck to respond with lower prices to avoid losing substantial market share.

141. In addition, the Merck Bundle has prevented physician practices and hospital purchasers from making a free choice between RotaTeq and Rotarix based on price, quality, service, and clinical preference.

142. On information and belief, Merck has executed these bundled loyalty contracts, requiring *de facto* exclusivity or near exclusivity on RotaTeq, with PBGs and other GPOs and hospital networks covering the vast majority of private physician and hospital purchasers of rotavirus vaccines in the United States. Under the terms of these contracts, physicians and hospital purchasers must purchase all or nearly all of their rotavirus vaccines from Merck to avoid substantial pricing penalties on all of Merck's vaccines. On information and belief, these contracts collectively foreclosed more than 40% of the Rotavirus Vaccine Market, which is a

substantial part of the available opportunities for the distribution of rotavirus vaccines in the United States.

IX. ANTICOMPETITIVE HARM AND ANTITRUST IMPACT

143. The purpose and effect of the RotaTeq bundled loyalty provision was to insulate Merck's RotaTeq from competition from GSK's Rotarix. By artificially dividing the market, Merck's bundled loyalty contracts prevented the price declines and market share erosion that would normally occur upon competitive entry into a market dominated by a monopolist, leading physicians and hospitals to pay more for RotaTeq than they otherwise would have.

144. As a result of Merck's bundled contracting scheme, plaintiff and members of the proposed class have repeatedly paid artificially inflated prices for rotavirus vaccines from the time Rotarix entered the market through the present.

A. Economic Theory Demonstrates How Merck's Bundled Loyalty Contracts Lead to Higher Prices

145. A member of economists have explained how bundled loyalty contracts can increase profits and anticompetitively raise prices, resulting in harm to consumers. Bundled loyalty contracts effectively function as market allocation agreements because they can result in the same outcome as would occur from horizontal agreements to divide customers, for example through a geographic market allocation agreement.²⁶

146. In a competitive marketplace without any bundled loyalty contracts, the entrance of a second product such as Rotarix to compete with a former monopolist would cause prices to

²⁶ See Einer Elhauge, *How Loyalty Discounts Can Perversely Discourage Discounting*, 5 J. Competition L. & Econ. 189 (2009); Einer Elhauge, *Tying, Bundled Discounts, and the Death of the Single Monopoly Profit Theory*, 123 Harv. L. Rev. 397, 459-61 (2009); Einer Elhauge & Abraham L. Wickelgren, *Robust Exclusion and Market Division Through Loyalty Discounts*, 43 Int'l. J. Indus. Org. 111 (2015).

drop. This is because, absent collusion, competing firms acting in their own rational self-interest will reduce their prices if by doing so they can gain or retain sufficient market share to offset the reduced profits or their existing sales due to the lower price. However, by imposing bundled loyalty conditions in its contracts, Merck prevented this normal price competition from occurring by effectively bifurcating the Rotavirus Vaccine Market into two groups: (1) restrained (foreclosed) buyers who are subject to the RotaTeq Bundled Loyalty Condition who purchased many other Merck pediatric vaccines, and thus would face high penalties on those vaccines if they did not buy RotaTeq (RotaTeq loyalists), and (2) unrestrained buyers who were not subject to the bundled loyalty condition or did not buy other Merck vaccines, and thus faced little to no penalty for switching to Rotarix. As described above, the first group of restrained buyers was foreclosed from purchasing Rotarix due to Merck's bundled loyalty contracts, while the second group of unrestrained buyers was not foreclosed.

147. Because the RotaTeq Bundled Loyalty Condition effectively divided the market in this way, it changed GSK's profit-maximizing strategy from the strategy it would have employed under normal competitive circumstances. Because it could not effectively price discriminate between restrained and unrestrained customers, GSK faced a choice: either (a) keep its price high but below the Merck disloyal RotaTeq price so that it could maximize its revenue on the unrestrained buyers that were willing to switch to Rotarix, or (b) reduce its price far below the loyal RotaTeq price in order to try to overcome the disloyalty penalties on Merck's other bundled vaccines so that GSK could try to convert some additional restrained customers, but earn significantly less revenue on its sales to unrestrained buyers because its price would be so much lower.

148. Given the size of the disloyalty penalties, and the fact that a significant portion of the demand for Merck's bundled vaccines is incontestable in the short run, Merck's bundled loyalty contracts were designed to foreclose a large enough share of the market to ensure that the profit-maximizing choice for GSK was to refrain from competing vigorously and instead compete at a high price for only the non-restrained customers who were not foreclosed. As a result, purchasers of RotaTeq were robbed of the benefits of competition due to Merck's bundled contracts and forced to pay higher prices.

149. Because Merck's bundled loyalty contracts reduced GSK's incentive to compete on price, the RotaTeq Bundled Loyalty Condition also caused increased Rotarix prices as well. That is, since the RotaTeq Bundled Loyalty Condition effectively divided the market in a way that lessened the incentives of GSK to compete with Merck, prices of both RotaTeq and Rotarix were higher than they would have been absent Merck's imposition of the RotaTeq Bundled Loyalty Condition. Prices were also increased market-wide for foreclosed and unforeclosed customers.

B. Bundling by GSK Would Not Mitigate the Anticompetitive Effects of the Market Division

150. To anticompetitively divide the Rotavirus Vaccine Market, the bundle need only foreclose a sufficient share of customers to reduce GSK's incentive to compete by reducing the price of Rotarix. If GSK responded by creating a parallel bundle with Rotarix and the other vaccines GSK sells, that would only reinforce the market-dividing effect of Merck's RotaTeq bundled loyalty contracts.²⁷ In that case, GSK would have even less incentive to cut prices on

²⁷ See, e.g., Einer Elhauge, *Tying, Bundled Discounts, and the Death of the Single Monopoly Profit Theory*, 123 Harv. L. Rev. 397, 475 (2009) ("having two firms use bundled loyalty discounts only worsens the extent to which their cumulative effect can discourage discounting"); Einer Elhauge, *How Loyalty Discounts Can Perversely Discourage Discounting*, 5 J.

Rotarix to retain GSK loyal customers because now such buyers would suffer bundled penalty prices on *other* GSK pediatric vaccines if those customers switched to RotaTeq. That in turn means that Merck would have even less incentive to try to cut RotaTeq prices to convert GSK loyal customers. GSK also could not cut Rotarix prices to Merck loyal customers without weakening the “stick” of eliminating the Rotarix loyalty discount as to those customers who are not loyal to GSK’s other pediatric vaccines. So GSK would now have even less incentive to target Merck loyal customers for Rotarix price cuts and Merck would have even less incentive to cut RotaTeq prices to Merck loyal customers. The net result would be an even more divided Rotavirus Vaccine Market with less price competition between Merck and GSK.

C. Instead of Decreasing RotaTeq Prices After Rotarix Entered the Rotavirus Vaccine Market, Merck Increased Prices or Kept Them Constant

151. Consistent with the economic theory discussed above, in response to new competition from Rotarix, Merck did not dramatically reduce prices as one would expect in a normal competitive market that had changed from a monopoly to a duopoly. Instead, Merck *raised* the price of RotaTeq.

152. The following table illustrates the private sector list price per dose for RotaTeq in each year since it was introduced in 2006. Merck’s anticompetitive conduct insulated it from competition, preventing prices from falling in response to the introduction of Rotarix in 2008 and instead allowing Merck to *increase* prices:

Date	Price per dose
Apr. 2006	\$63.25

Competition L. & Econ. 189, 194, 214-15, 220 (2009) (“I extend the analysis to cases where multiple firms offer loyalty discounts with commitments, and prove that this exacerbates the anticompetitive effects. The resulting cumulative foreclosure leaves fewer uncommitted buyers available, and thus creates even less incentive for either firm to undercut uncommitted prices to get them, given that doing so would reduce the committed prices of each firm.”).

May 2007	\$66.94
Sept. 2008	\$69.59
Dec. 2009	\$65.59
Dec. 2010	\$69.59
Dec. 2011	\$69.59
Nov. 2012	\$72.34
Nov. 2013	\$75.20
Dec. 2014	\$75.20
Nov. 2015	\$78.18
Dec. 2016	\$81.28
Dec. 2017	\$82.89

X. CONTINUING VIOLATION

153. From 2008 and continuing to the present day, Merck has enforced and threatened to enforce the terms of its exclusionary bundled loyalty contracts.

154. From 2008 and continuing to the present day, Merck has enforced and threatened to enforce the terms of its exclusionary bundled loyalty contracts.

155. From 2008 and continuing to the present day, Merck's anticompetitive scheme has allowed it to repeatedly overcharge customers for RotaTeq, with each sale causing additional anticompetitive harm.

XI. CLASS ACTION ALLEGATIONS

156. Plaintiff brings this action on behalf of itself and all others similarly situated pursuant to Rule 23 of the Federal Rules of Civil Procedure as representative of a class defined as follows:

All persons or entities in the United States and its territories that purchased RotaTeq directly from Merck or any of its divisions, subsidiaries, predecessors, or affiliates, during the period from April 25, 2014 through such time as the effects of Merck's illegal conduct have ceased, and excluding all governmental entities, Merck, and Merck's divisions, subsidiaries, predecessors, and any purchases by entities buying RotaTeq pursuant to a publicly-negotiated price (*i.e.*, governmental purchasers).

157. On information and belief, hundreds or thousands of entities in the United States have purchased RotaTeq directly from Merck. Thus, the class is so numerous that joinder is impracticable.

158. Plaintiff's claims are typical to those of the class.

159. Plaintiff and all members of the class were injured in the form of overcharges by the same conduct of the defendant.

160. Plaintiff will fairly and adequately protect and represent the interests of the class. The interests of the plaintiff are not antagonistic to the class.

161. Plaintiff is represented by counsel who are experienced and competent in the prosecution of complex class action antitrust litigation.

162. Questions of law and fact common to the members of the class predominate over questions, if any, that may affect only individual members because Merck has acted and refused to act on grounds generally applicable to the entire class. Such generally applicable conduct is inherent in Merck's exclusionary and anticompetitive conduct in monopolizing and attempting to monopolize the Rotavirus Vaccine Market, as more fully alleged therein.

163. Questions of law and fact common to the class include:

- a. whether Merck intentionally and unlawfully impaired or impeded competition in the Rotavirus Vaccine Market;
- b. whether Merck maintained or enhanced monopoly power in the Rotavirus Vaccine Market;
- c. whether Merck engaged in anticompetitive conduct in order to unlawfully disadvantage its competitors and maintain monopoly power in the Rotavirus Vaccine Market;
- d. whether Merck had and has monopoly power in the MMR, Varicella, HPV, and Rotavirus Vaccine Markets;
- e. whether Merck had precompetitive reasons for its conduct;
- f. the effects of Merck's anticompetitive conduct on rotavirus vaccine prices;
- g. whether plaintiff and other members of the class have been overcharged and thus damaged by paying artificially inflated prices for rotavirus vaccines as a result of Merck's unlawful behavior; and

h. the proper measure of damages.

164. Class action treatment is a superior method for the fair and efficient adjudication of the controversy in that, among other things, such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of effort and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress for claims that might not be practicable for them to pursue individually, substantially outweigh any difficulties that may arise in management of this class action.

165. Plaintiff knows of no difficulty to be encountered in the maintenance of this action as a class action.

FIRST CAUSE OF ACTION
Monopolization of the Rotavirus Vaccine Market (15 U.S.C. § 2)

166. Plaintiff incorporates by reference the above allegations.

167. At all relevant times, Merck had monopoly power in the MMR, Varicella, HPV, and Rotavirus Vaccine Markets. During much of the relevant period, Merck had market power in the hepatitis A, hepatitis B, and Hib pediatric vaccine markets.

168. Merck has willfully maintained its monopoly power in the Rotavirus Vaccine Market through exclusionary and anticompetitive means. Merck leveraged its monopoly power in the MMR, Varicella, HPV, and Rotavirus Vaccine Markets by imposing contractual terms on purchasers of its vaccines that penalized customers for buying vaccines from rivals such as GSK. Since at least 2008, Merck's exclusionary contracts have unfairly impaired the incentive of rivals such as GSK to compete for market share, and have thus preserved Merck's monopoly power in the market for rotavirus vaccines.

169. By engaging in this exclusionary conduct, Merck has gained an artificial and unlawful advantage from its monopoly power in a variety of vaccine markets, as opposed to by offering products with lower prices or higher quality. As a result, Merck has unfairly impeded competition in the Rotavirus Vaccine Market. The purpose and effect of Merck's conduct has been to suppress competition rather than to promote it.

170. By suppressing competition and maintaining its monopoly power, Merck has been able to artificially inflate the price of RotaTeq above levels that would have prevailed in a world without Merck's anticompetitive conduct alleged herein. In addition, because Merck's conduct removed price cutting as an effective competitive response for GSK, Rotarix's price was higher than it otherwise would have been. Accordingly, the challenged conduct caused plaintiff and members of the proposed class to pay artificially inflated prices for rotavirus vaccines sold into the private market.

171. There are no procompetitive justifications for Merck's conduct.

172. Plaintiffs have been injured in their business and property by reason of Merck's unlawful monopolization. Plaintiff's injuries consist of paying higher prices to purchase rotavirus vaccines than they would have paid absent Merck's unlawful conduct as alleged herein. Plaintiff's injuries are of the type the antitrust laws were designed to prevent and flow from that which makes Merck's conduct unlawful.

SECOND CAUSE OF ACTION
Anticompetitive Agreements in Unreasonable Restraint of Trade (15 U.S.C. § 1)

173. Plaintiff incorporates by reference the above allegations.

174. At all relevant times, Merck had monopoly power in the MMR, Varicella, HPV, and Rotavirus Vaccine Markets. During much of the relevant period, Merck had market power in the hepatitis A and hepatitis B pediatric vaccine markets.

175. Merck entered into a series of unlawful exclusionary agreements with PBGs, hospital groups, and other GPOs whose purpose and effect was to unreasonably restrain competition in the Rotavirus Vaccine Market by penalizing customers with high prices on a portfolio of vaccines if the customer did not agree to refrain from purchasing rotavirus vaccines from Merck's rivals.

176. Merck entered into agreements with PBGs to enforce its exclusionary bundled vaccine pricing scheme. These agreements included written exclusionary agreements in unreasonable restraint of trade, which included various exclusionary contractual terms.

177. There was no legitimate business justification for these agreements and these agreements: (a) substantially foreclosed and excluded competition from rotavirus vaccine manufacturers; and (b) resulted in Merck's willful maintenance and unlawful exercise of monopoly power in the Rotavirus Vaccine Market.

178. At all relevant times, Merck's exclusionary agreements assisted Merck in: (a) effectively excluding less expensive competitive products from the Rotavirus Vaccine Market; (b) maintaining Merck's dominant market share and monopoly power in the Rotavirus Vaccine Market; (c) maintaining prices at artificially high levels for RotaTeq; and (d) otherwise reaping the benefits of its illegal monopoly power.

179. There is no precompetitive justification for Merck's conduct.

180. Plaintiff has been injured in its business and property by reason of the alleged collusion and conspiracy, which facilitated, enabled, assisted, and furthered Merck's substantial foreclosure and exclusion of competition and monopolization of the Rotavirus Vaccine Market. Plaintiff's injuries consist of paying higher prices to purchase the relevant products than they

would have paid absent Merck's unlawful conduct. Plaintiff's injuries are the type the antitrust laws were designed to prevent and flow from that which makes Merck's conduct unlawful.

PETITION FOR RELIEF

WHEREFORE, plaintiff petitions that:

181. The Court determine that this action may be maintained as a class action pursuant to Federal Rule of Civil Procedure 23, that plaintiff be appointed as class representative, and that plaintiff's counsel be appointed as counsel for the class;

182. The conduct alleged herein be declared, adjudged, and/or decreed to be unlawful under Section 1 and Section 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2;

183. Plaintiff and the class recover their overcharge damages, trebled, and the costs of the suit, including reasonable attorneys' fees as provided by law; and

184. Plaintiff and the class be granted such other and different relief as the nature of the case may require or as may be determined to be just, equitable, and proper by this Court.

JURY TRIAL DEMANDED

185. Plaintiff demands a trial by jury on all of the claims asserted in this Complaint so triable.

EDELSON & ASSOCIATES, LLC

Dated: July 23, 2018



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